

**REMARKS**

Claims 30 and 36-46 are pending in the application. Claims 30 and 36-45 have been amended to clarify the subject matter which Applicant regards as the invention. Claim 44 has also been amended so as to recite concentration ranges described in the specification. Claim 46 has been added. Support for these amendments can be found in the specification and no new matter has been added.

**I. SUMMARY OF INTERVIEW**

Applicant would like to express appreciation for the interview conducted on October 15, 2007. In this interview, Applicant's representatives, Cathryn Campbell and Kevin Hathcock, discussed the rejections contained in the Office Action of June 22, 2007, with Examiner Pak. Applicant's representatives discussed the Srivastava reference and the differences between trisilver citrate and the inventive silver dihydrogen citrate of the present invention.

**II. REJECTIONS UNDER 35 U.S.C. § 112, 1<sup>st</sup> PARAGRAPH**

**a. Rejection of Claims 30 and 36-45**

The Office Action has rejected claims 30 and 36-45 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the rejected claims contain subject matter not described in the specification in such a way as to reasonably convey the invention to one of skill in the art. Applicant respectfully disagrees with this rejection for the following reasons.

Based on the interview with Examiner Pak, as described above, Applicant understands this rejection to be based on the premise that the present claims directed to compositions of matter do not incorporate specific process limitations related to an electrolytic method of production, and are thus new matter. Applicant maintains that adequate written description to support the present claims exists in the as-filed specification.

The recited electrolytic process for preparing a silver dihydrogen citrate composition is not critical to the present invention, and the present invention is not limited to a particular process for preparing the composition. The rejected claims of the present application are directed

to compositions of matter and not to a product by process. Thus, the claims do not require incorporation of a limitation to a specific process of making the composition.

Applicant describes in the specification a highly efficient and industrially practical method of producing a unique chemical compound, i.e. silver dihydrogen citrate, along with methods for making and using compositions comprising silver dihydrogen citrate. The electrolytic method of synthesis described by Applicant is sufficient to enable the public to both make and use the full range of claimed compositions and methods for their use, as required by 35 U.S.C. § 112. A claim directed to a product is properly supported by an adequate written description and enabling disclosure, even if it describes only one method of making the claimed product. *See Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1308 (Fed. Cir. 2001); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998); and *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991). Thus, Applicant is not required to amend the composition claims to include the electrolytic process described in the specification of the present application.

Applicant has fulfilled their obligation by providing a written description of a process for making the composition. Accordingly, this rejection should be withdrawn.

**b. Rejection of Claims 38-40**

The Office Action has rejected claims 38-40 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the inclusion and/or removal of a percentage unit is deemed to be new matter without support in the specification. Applicant respectfully disagrees with this rejection for the following reasons.

The Office Action incorrectly assumes that all recitations of percent in the specification refer to volume percent. As the Office Action correctly notes, neither the inventive  $\text{Ag}^+\text{CA}^-$  complex nor citric acid is a liquid at ambient temperature. While it is possible to refer to the concentration of a dissolved solid in a liquid in terms of either a volume % or a weight %, one of skill in the art would understand that where a percent “%” is recited without a specific unit (e.g., page 23, lines 1-4 of the as-filed specification), that such a percentage is intended to refer to a weight percent. Thus, in the present application, specific recitations of volume percent are

intended to refer to a volume percent, whereas recitations of percent without a unit are intended to refer to a weight percent.

In addition to the remarks above, Applicant refers Examiner to U.S. Patent No. 6,583,176 (Attorney Docket No. 16200.0006U3), of which the present application is a divisional thereof. Issued claims 3-5 and 7-9 of U.S. Patent No. 6,583,176, based on the same disclosure as that of the present application, recite percent by weight. In accordance with these remarks and to clarify the subject matter which Applicant regards as the invention, Claims 38-40 have been amended to include the specific recitation of a weight percent (wt. %). Moreover, claims 41-45 have been amended as described herein, to specifically refer to a weight percent. For the reasons described herein, none of the claims as previously presented or as amended herein incorporate new matter. Accordingly, this rejection should be withdrawn.

**c. Rejection of Claims 44-45**

The Office Action has rejected claims 44-45 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that the specification fails to disclose the combination of citric acid concentrations and silver citrate concentrations recited in the rejected claims. Applicant respectfully disagrees with this rejection for the following reasons.

Claim 44, as amended, recites the aqueous solution of claim 30 comprising from greater than 1.0 % to 10% by weight citric acid, and from 4.27 ppm to 300 ppm of the complex having the formula:  $\text{Ag}^+\text{CA}^-$ . Support for this amendment can be found throughout the specification, including for example, at page 23, lines 1-20.

New claim 46 has been added to recite the specific combination of at least 0.1% by weight citric acid, and at least 4.27 ppm of the complex having the formula:  $\text{Ag}^+\text{CA}^-$ . Support for this claim can be found at page 25, line 3 of the originally filed specification. In view of these amendments, this rejection should be withdrawn.

**III. REJECTIONS UNDER 35 U.S.C. § 112, 2<sup>nd</sup> PARAGRAPH**

**a. Rejection of Claims 30 and 36-45**

The Office Action has rejected claims 30 and 36-45 under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential elements, namely an electrolytic process step for preparing the claimed composition. Applicant respectfully disagrees with this rejection for the following reasons.

As an initial matter, the silver dihydrogen citrate of the present invention is a novel composition, as distinguished from the trisilver citrate composition known in the art. Conventional trisilver citrate has three silver ions per citric acid anion, while the inventive silver dihydrogen citrate of the present invention has one silver ion per citric acid anion, together with two protons. The previously submitted Declaration under 37 C.F.R. § 1.132 by Professor David Pullman (hereinafter “Pullman”) demonstrates the distinctions between these compositions.

In addition to the distinctions between trisilver citrate and the inventive silver dihydrogen citrate described by Pullman, the recited electrolytic process for preparing a silver dihydrogen citrate composition is not critical to the present invention, and the present invention is not limited to a particular process for preparing the composition. The rejected claims of the present application are directed to compositions of matter and not to a product by process. Thus, the claims do not require incorporation of a limitation to a specific process of making the composition.

Applicant describes in their specification a highly efficient and industrially practical method of producing a unique chemical compound, i.e. silver dihydrogen citrate, along with methods for making and using compositions comprising silver dihydrogen citrate. The electrolytic method of synthesis described by Applicant is sufficient to enable the public to both make and use the full range of claimed compositions and methods for their use, as required by 35 U.S.C. § 112. A claim directed to a product is properly supported by an adequate written description and enabling disclosure, even if it describes only one method of making the claimed product. *See Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1308 (Fed. Cir. 2001); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998); and *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991). Thus, Applicant is not required to amend

the composition claims to include the electrolytic process described in the specification of the present application.

Applicant has fulfilled their obligations by providing a written description of a process for making the composition. The claims of the present invention are complete and do not omit any essential elements. Accordingly, this rejection should be withdrawn.

**b. Rejection of Claims 30 and 36-37**

While not specifically rejected, the Office Action alleges that claims 30 and 36-37 are confusing for reciting an aqueous solution of citric acid comprising the  $\text{Ag}^+\text{CA}^-$  complex. Applicant respectfully disagrees with this assertion. As amended, claims 30 and 36-37 recite an aqueous solution comprising citric acid and a complex having the formula  $\text{Ag}^+\text{CA}^-$ , wherein  $\text{CA}^-$  is the citric acid anion. Thus, in the event that this allegation was intended to be a rejection, the rejection should be withdrawn.

**IV. REJECTIONS UNDER 35 U.S.C. § 102(b)**

The Office Action has rejected claims 30 and 36-40 under 35 U.S.C. § 102(b), as allegedly being anticipated by Srivastava et al. Applicant respectfully disagrees with this rejection for the following reasons.

Applicant previously submitted a Declaration under 37 C.F.R. § 1.132 by Professor David Pullman (hereinafter “Pullman”), in which Dr. Pullman provides scientific support for the conclusion that Srivastava’s silver citrate was either “only partially dissolved, so the actual concentration in solution was less than 0.5%” or “0.5% was a typographical error.” This conclusion is also supported by the following facts.

Trisilver citrate was the only known and reported silver citrate compound to have existed at the time Srivastava was published. In addition, Srivastava failed to specifically recite the silver dihydrogen citrate of the present invention. Srivastava is directed towards the development of surgical gauze and absorbent cotton using existing materials and not to the development of novel silver compounds. Thus, if Srivastava had in fact developed a novel silver compound for use on antiseptic dressings, one of skill in the art would expect a specific notation of such a discovery, along with a description of the compound and/or the method of making. In

contrast, no such notation is made and no description of the silver citrate material or the method of making the same is disclosed. Moreover, the surgical gauze treated with the silver citrate solution of Srivastava failed to exhibit the bactericidal activity expected for the inventive silver dihydrogen citrate composition.

Despite the strong scientific support for Dr. Pullman's conclusions, the Office Action maintains the assertion that Srivastava inherently possessed the silver dihydrogen citrate composition of the present invention. The Office Action further alleges that the pH dependent solubility of trisilver citrate, as described in Exhibit F of Pullman (Merck Index), supports the allegation that the solubility values reported in Srivastava were correct; however, Srivastava fails to disclose the presence of nitric acid and/or ammonia in the silver citrate solution that could facilitate the reported solubility values. In contrast, the silver chloride solutions described in Srivastava are specifically denoted as "Ammoniacal silver chloride." One of skill in the art would thus expect the description of silver citrate to include some reference to nitric acid and/or ammonia, if present. By conspicuous absence, neither of these species are disclosed. Moreover, even if Srivastava disclosed a trisilver citrate made soluble by the addition of, for example, nitric acid and/or ammonia, Srivastava would still fail to disclose the novel silver dihydrogen citrate of the present invention.

One of skill in the art would not typically treat an absorbent cotton surgical gauze with nitric acid and/or ammonia, as these species can potentially injure any tissue in which they contact. To this end, Srivastava specifically mentions that antibiotics were purposely avoided due to, in part, their skin sensitization potential.

The Office Action further alleges that silver dihydrogen citrate could be present in the Srivastava solution due to equilibrium effects, yet the mass spectrometry data described in Pullman specifically points out that no detectable level of silver dihydrogen citrate was observed in a trisilver citrate solution.

The scientific support for the conclusions of Dr. Pullman is well grounded. In contrast, Srivastava fails to disclose either the silver dihydrogen citrate or any combination of disclosure and data to support the anticipation allegations in the Office Action. Accordingly, this rejection should be withdrawn.

**V. REJECTIONS UNDER 35 U.S.C. § 103(a)**

The Office Action has rejected claims 30 and 36-45 under 35 U.S.C. § 103(a), as allegedly being obvious over U.S. Patent No. 6,838,095 to Newman et al. (hereinafter “Newman”). Applicant respectfully disagrees with this rejection for the following reasons.

As an initial matter, the present application ultimately claims priority to U.S. Patent Application No. 60/061,673, filed on October 10, 1997. The Office Action alleges that the application currently contains new matter, thus allowing Newman to qualify as a prior art reference for this rejection. As described in the remarks above, the present application does not include new matter, and thus, Newman cannot be used to support a rejection in the present application. Accordingly, this rejection should be withdrawn.

**VI. OBVIOUSNESS TYPE DOUBLE PATENTING REJECTIONS**

**a. Rejection of Claims 30 and 36-45 over U.S. Patent No. 6,197,814**

The Office Action has rejected claims 30 and 36-45 under the judicially created doctrine of obviousness type double patenting over claims 1-17 of U.S. Patent No. 6,197,814 (hereinafter “the ‘814 patent”; Attorney Docket No. 16200.0006U2). While not admitting that the rejected claims are obvious over claims 1-17 of the ‘814 patent, Applicant respectfully requests that this rejection be held in abeyance until the other rejections addressed herein have been overcome.

**b. Rejection of Claims 30 and 36-45 over U.S. Patent Application No. 10/936,465**

The Office Action has provisionally rejected claims 30 and 36-45 under the judicially created doctrine of obviousness type double patenting over claims 1, 4, 9, 18-19, and 30-32 of copending application 10/936,465 (hereinafter “the ‘465 application”; Attorney Docket No. 16200.0001U1). This rejection is provisional as the claims of the ‘465 application have not been allowed. While not admitting that the rejected claims are obvious over claims 1, 4, 9, 18-19, and 30-32 of the ‘465 application, Applicant respectfully requests that this provisional rejection be held in abeyance and that, if the other rejections addressed herein have been overcome, the claims of the present application be allowed.

**c. Rejection of Claims 30 and 36-45 over U.S. Patent Application No. 11/144,398**

The Office Action has provisionally rejected claims 30 and 36-45 under the judicially created doctrine of obviousness type double patenting over claims 1, 4, 9, 18-19, and 30-32 of copending application 11/144,398 (hereinafter “the ‘398 application”; Attorney Docket No. 16200.0001U2). This rejection is provisional as the claims of the ‘398 application have not been allowed. While not admitting that the rejected claims are obvious over claims 1, 4, 9, 18-19, and 30-32 of the ‘398 application, Applicant respectfully requests that this provisional rejection be held in abeyance and that, if the other rejections addressed herein have been overcome, the claims of the present application be allowed.

**d. Rejection of Claims 30 and 36-45 over U.S. Patent Application No. 11/729,175**

The Office Action has provisionally rejected claims 30 and 36-45 under the judicially created doctrine of obviousness type double patenting over claim 1 of copending application 11/729,175 (hereinafter “the ‘175 application”; Attorney Docket No. 16200.0003U5). This rejection is provisional as the claims of the ‘175 application have not been allowed. While not admitting that the rejected claims are obvious over claim 1 of the ‘175 application, Applicant respectfully requests that this provisional rejection be held in abeyance and that, if the other rejections addressed herein have been overcome, the claims of the present application be allowed.

**e. Rejection of Claims 30 and 36-45 over U.S. Patent Application No. 11/407,654**

The Office Action has provisionally rejected claims 30 and 36-45 under the judicially created doctrine of obviousness type double patenting over claims 16-19, 21-24, and 31 of copending application 11/407,654 (hereinafter “the ‘654 application”; Attorney Docket No. 16200.0002U2). This rejection is provisional as the claims of the ‘654 application have not been allowed. While not admitting that the rejected claims are obvious over claims 16-19, 21-24, and 31 of the ‘654 application, Applicant respectfully requests that this provisional rejection be held in abeyance and that, if the other rejections addressed herein have been overcome, the claims of the present application be allowed.



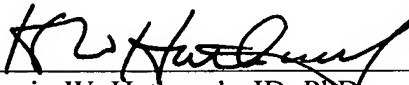
**CONCLUSION**

Pursuant to the above Remarks and in view of the offered claim amendments, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Payment is herewith submitted via Credit Card Payment Form PTO-2038 in the amount of \$1,050 for a three-month extension of time under 37 C.F.R. § 1.17(a)(3). This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

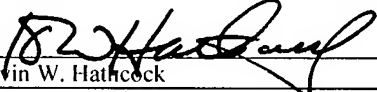
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**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8**

I hereby certify that this correspondence and the documents mentioned therein are being deposited with the United States Postal Service in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450, on the date indicated below

  
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Kevin W. Hathcock

12-20-2007  
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Date